Message

From: Dunton, Cheryl [Dunton.Cheryl@epa.gov]
Sent: 12/8/2021 3:05:45 PM
To: Ozmen, Shamus [Ozmen.Shamus@epa.gov]; Goodis, Michael [Goodis.Michael@epa.gov]
CC: Messina, Edward [Messina.Edward@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Cyran, Carissa [Cyran.Carissa@epa.gov]
Subject: RE: OCSPP IO Press Inquiry - E&E New re: Glyphosate

Ex. 5 Deliberative Process (DP)

From: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Sent: Wednesday, December 8, 2021 10:04 AM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>
Subject: RE: OCSPP IO Press Inquiry - E&E New re: Glyphosate

Ex. 5 Deliberative Process (DP)

RESPONSE:

EPA is not a party to this litigation.

Enclosed is information related to EPA's review of glyphosate.

On January 27, 2020, EPA released the glyphosate Interim Decision (ID) for registration review. As part of this action, EPA continues to find that there are no risks of concern to human health when glyphosate is used in accordance with current product labels. EPA also conducted an independent evaluation of the human carcinogenic potential of glyphosate as part of registration review and concluded that glyphosate is not likely to be a human carcinogen. EPA's comprehensive evaluation, which is described in EPA's *Revised Issue Paper: Evaluation of Carcinogenic Potential*, included an in-depth review of an extensive database of relevant studies submitted to the EPA or published in the open literature. EPA's cancer classification is in line with recent findings by many international expert panels and regulatory authorities, such as the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan and the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues.

On August 9, 2019, EPA issued guidance to registrants of glyphosate to ensure clarity on labeling of the chemical on their products. EPA no longer approves product labels claiming glyphosate is known to cause cancer – a false claim that does not meet the labeling requirements of the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA).

On November 12, 2021, EPA completed the next step in the registration review process and released the final glyphosate Biological Evaluation (BE) along with a summary of comments received on the draft BE and EPA's responses. In addition to evaluating toxicity and estimated exposure, the BE considered where glyphosate can be legally applied and compared this information to the ranges of listed species. The BE also evaluated potential impacts of sublethal toxic effects and effects that are not due to direct toxicity (*e.g.,* habitat

modification). Currently, EPA is evaluating whether additional mitigation is needed to address ecological risks beyond what was required in the glyphosate ID.

The glyphosate registration review docket EPA-HQ-OPP-2009 0361 at www.regulations.gov includes all supporting documents EPA used to make the registration review interim decision. Additionally, all documents related to the 2016 FIFRA Scientific Advisory Panel (SAP) on EPA's Evaluation of Glyphosate's Carcinogenic Potential can be found in docket EPA-HQ-OPP-2016-0385 at www.regulations.gov. Information on glyphosate can also be found EPA's website.

Thank you,

Shamus Ozmen
Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Mobile: (571) 442-9844

From: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Sent: Wednesday, December 8, 2021 9:55 AM
To: Goodis, Michael <Goodis.Michael@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>
Subject: RE: OCSPP IO Press Inquiry - E&E New re: Glyphosate

Ex. 5 Deliberative Process (DP)

From: Goodis, Michael <Goodis.Michael@epa.gov>
Sent: Wednesday, December 8, 2021 9:49 AM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>
Subject: RE: OCSPP IO Press Inquiry - E&E New re: Glyphosate

Ex. 5 Deliberative Process (DP)

Michael L. Goodis, P.E.
Acting Deputy Director for Programs
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Washington, D.C.
571-309-5497 (cell)

From: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Sent: Wednesday, December 08, 2021 9:45 AM
To: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>
Subject: RE: OCSPP IO Press Inquiry - E&E New re: Glyphosate

Ex. 5 Deliberative Process (DP)

From: Ozmen, Shamus <Ozmen.Shamus@epa.gov>
Sent: Tuesday, December 7, 2021 5:07 PM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Cc: Messina, Edward <Messina.Edward@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>; Cyran, Carissa <Cyran.Carissa@epa.gov>
Subject: OCSPP IO Press Inquiry - E&E New re: Glyphosate

Hi Cheryl,

Please find for your review the response concerning EPA's current moves and findings for glyphosate.

INCOMING:

I'm working on a story about the Monsanto v. Hardeman Supreme Court petition related to the $25 million jury verdict for Edwin Hardeman in the Roundup cancer case.

A lot of Monsanto's claims hinge on the EPA's authorization of the sale of Roundup, approval of Roundup sales without a cancer warning and finding that a cancer warning would "misbrand" the product.

Can someone help me understand EPA's latest moves on Roundup and glyphosate? I want to make sure I'm correctly characterizing the agency's current findings.

RESPONSE:

EPA is not a party to this litigation.

Enclosed is information related to EPA's review of glyphosate.

On January 27, 2020, EPA released the glyphosate Interim Decision (ID) for registration review. As part of this action, EPA continues to find that there are no risks of concern to human health when glyphosate is used in accordance with current product labels. EPA also conducted an independent evaluation of the human carcinogenic potential of glyphosate as part of registration review and concluded that glyphosate is not likely to be a human carcinogen. EPA's comprehensive evaluation, which is described in EPA's *Revised Issue Paper: Evaluation of Carcinogenic Potential,* included an in-depth review of an extensive database of relevant studies submitted to the EPA or published in the open literature. EPA's cancer classification is in line with recent findings by many international expert panels and regulatory authorities, such as the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, European Food Safety Authority, German Federal Institute for Occupational Safety and Health, New Zealand Environmental Protection Authority, and the Food Safety Commission of Japan and the Joint Food and Agriculture Organization/World Health Organization Meeting on Pesticide Residues

On November 12, 2021, EPA completed the next step in the registration review process and released the final glyphosate Biological Evaluation (BE) along with a summary of comments received on the draft BE and EPA's responses. In addition to evaluating toxicity and estimated exposure, the BE considered where glyphosate can be legally applied and compared this information to the ranges of listed species. The BE also evaluated potential impacts of sublethal toxic effects and effects that are not due to direct toxicity (*e.g.,* habitat modification). Currently, EPA is evaluating whether additional mitigation is needed to address ecological risks beyond what was required in the glyphosate ID.

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Thank you,

Shamus Ozmen
Communications Branch
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Mobile: (571) 442-9844

From: Milbourn, Cathy <Milbourn.Cathy@epa.gov>
Sent: Tuesday, December 7, 2021 11:25 AM
To: Dunton, Cheryl <Dunton.Cheryl@epa.gov>; Scheifele, Hans <Scheifele.Hans@epa.gov>
Cc: OPS CSID CB <OPS_CSID_CB@epa.gov>
Subject: E&E News--Deadline today -- Glyphosate

Hi Cheryl and Hans,

I'm sure we won't have much to say—please let me know.

Thanks,

Cathy

From: Pamela King <pking@eenews.net>
Sent: Tuesday, December 7, 2021 7:44 AM
To: EPA Press Office <Press@epa.gov>
Subject: Deadline today -- Glyphosate

Good morning,

I'm working on a story about the Monsanto v. Hardeman Supreme Court petition related to the $25 million jury verdict for Edwin Hardeman in the Roundup cancer case.

A lot of Monsanto's claims hinge on the EPA's authorization of the sale of Roundup, approval of Roundup sales without a cancer warning and finding that a cancer warning would "misbrand" the product.

Can someone help me understand EPA's latest moves on Roundup and glyphosate? I want to make sure I'm correctly characterizing the agency's current findings.

Thank you,

Pamela King

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